October 15, 2002

Wendy K. Sherman
Technical Contact
The American Chemistry Council
Brominated Flame Retardant Industry Panel
1300 Wilson Boulevard
Arlington, VA 22209

Dear Ms. Sherman:

The Office of Pollution and Toxics is transmitting EPA's comments on the robust summaries and test plan for Phenol, 4,4'-Isopropylidenbis[2,6-dibromo- posted on the ChemRTK HPV Challenge Program Web site on February 5, 2002. I commend The American Chemistry Council Brominated Flame Retardant Industry Panel for its commitment to the HPV Challenge Program.

EPA reviews test plans and robust summaries to determine whether the reported data and test plans will provide the data necessary to adequately characterize each SIDS endpoint. On its Challenge Web site, EPA has provided guidance for determining the adequacy of data and preparing test plans used to prioritize chemicals for further work.

We would like to note that, as indicated above, EPA's review was limited to a determination of data adequacy and not to an interpretation of the submitted data. As you are aware, the United Kingdom (UK) has sponsored this chemical in the OECD/SIDS Program and in the future will be presenting an assessment document for review by OECD member states. At that time, EPA will offer comments on the interpretation of the data as presented in the UK assessment document.

EPA will post this letter and the enclosed comments on the HPV Challenge Web site within the next few days. As noted in the comments, we ask that The American Chemistry Council Brominated Flame Retardant Industry Panel advise the Agency, within 60 days of this posting on the Web site, of any modifications to its submission.

If you have any questions about this response, please contact Richard Hefter, Chief of the HPV Chemicals Branch, at 202-564-7649. Submit questions about the HPV Challenge Program through the HPV Challenge Program Web site "Submit Technical Questions" button or through the TSCA Assistance Information Service (TSCA Hotline) at (202) 554-1404. The TSCA Hotline can also be reached by e-mail at tsca-hotline@epa.gov.

I thank you for your submission and look forward to your continued participation in the HPV Challenge Program.

Sincerely,

-S-

Oscar Hernandez, Director
Risk Assessment Division

Enclosure

cc: C. Auer
A. Abramson
W. Penberthy
M. E. Weber

EPA COMMENTS ON CHEMICAL RTK CHALLENGE SUBMISSION:
4,4'-ISOPROPYLIDENEBIS(2,6-DIBROMOPHENOL)

SUMMARY OF EPA COMMENTS

The sponsor, the Brominated Flame Retardant Industry Panel of the American Chemistry Council, submitted a test plan and robust summaries for 4,4'-isopropylidenebis(2,6-dibromophenol) (CAS No. 79-94-7) to EPA. EPA posted the submission on the Chemical RTK HPV Challenge Web site on February 5, 2002.

EPA has reviewed this submission and has reached the following conclusions:

1. Physicochemical Properties and Environmental Fate. The submitter needs to provide data for boiling point, photodegradation and stability in water in robust summary format.

2. Health Effects. All appropriate SIDS-level endpoints have been addressed except for reproductive toxicity.

3. Ecological Effects. All appropriate SIDS-level endpoints have been addressed. However, the submitter needs to provide robust summaries for certain endpoints and to address deficiencies in robust summaries for the remaining endpoints.

EPA requests that the submitter advise the Agency within 60 days of any modifications to its submission.

EPA COMMENTS ON THE 4,4'-ISOPROPYLIDENEBIS(2,6-DIBROMOPHENOL) CHALLENGE SUBMISSION

Test Plan

Physicochemical Properties (*melting point, boiling point, vapor pressure, water solubility, and partition coefficient).*

The data provided by the submitter for melting point, vapor pressure, partition coefficient, and water solubility are adequate for the purposes of the HPV Challenge Program.

Boiling Point. The submitter did not provide boiling point data in the robust summaries. According to OECD Guideline 103, boiling points above 300 °C do not have to be determined. However, the submitter needs to provide a robust summary addressing this endpoint, and also indicate if there is a decomposition temperature for this chemical.

Environmental Fate *(photodegradation, stability in water, biodegradation, fugacity).*

The data provided by the submitter for biodegradation and transport and distribution are adequate for the purposes of the HPV Challenge Program.

Stability in water. The submitter did not provide a robust summary for this endpoint. Even though this chemical may not undergo hydrolysis, the submitter needs to provide a technical discussion addressing this issue in robust summary format.

Photodegradation. The submitter needs to provide data for this endpoint in robust summary format. It is not sufficient to provide data only in the test plan.

Health Effects *(acute toxicity, repeated-dose toxicity, genetic toxicity, and reproductive/developmental toxicity).*

Test data are adequate for all endpoints except for reproductive toxicity.

Reproductive Toxicity. Data on reproductive toxicity were not provided. The submitter considers the five repeated-dose and four developmental toxicity studies sufficient to demonstrate that reproductive effects are unlikely. Only one of the repeated-dose studies (90-day mouse study) had sufficient exposure duration and concentration to address reproductive toxicity but histopathology data were not given. If histopathology data on the reproductive organs are provided and they show no adverse affects, EPA would concur that a reproductive toxicity test is not needed for the purposes of the HPV Challenge Program.

Ecological Effects *(fish, invertebrates, and algae)*.

No ecotoxicity testing is necessary provided that robust summaries for the fish acute and chronic toxicity studies and the daphnid chronic toxicity study are submitted.

Specific Comments on the Robust Summaries

Physicochemical Properties

Melting Point. The submitter did not provide test guideline information or test methods in the robust summary for this endpoint.

Health Effects

Reproductive Toxicity. The submitter needs to provide a separate robust summary for this endpoint.

Ecological Effects

Fish. The submitter needs to provide the missing robust summaries for the fish acute and chronic toxicity studies.

Invertebrates. The submitter needs to provide the missing robust summary for the chronic daphnia study and detailed information on test conditions (i.e., mortality, DO, pH, and measured/nominal concentrations) for the other aquatic invertebrate studies.

Algae. The submitter needs to provide detailed information on test conditions (i.e., test concentrations for the marine species, replicate numbers, the initial cell concentrations, and the increase of cell concentrations in controls).

Followup Activity

EPA requests that the submitter advise the Agency within 60 days of any modifications to its submission.